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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,169	07/15/2003	Michael J. Grusby	22058-585 (AM 101001L/H.U)	1105
30623	7590	07/29/2005	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,169

Applicant(s)

GRUSBY ET AL.

Examiner

Fozia M. Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/05/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 05/05/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

Election/Restrictions:

1. Applicants' election with traverse of the invention of Group II (claims 11-23) filed on 05 May 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-23 are under consideration.

Claims 1-10 are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions.

Claim Rejections Under 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2a. Claims 11-16, 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention.

Claims 11-16, 18-23 are rejected as containing subject matter not described in the specification because they encompass antagonists of IL-21 or IL-21 receptor, whose structure has not been described in the instant specification. Claims 11 and 13 recite IL-21/IL-21receptor antagonists selected from the group consisting of anti-IL-21R antibody,

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an antigen-binding fragment of an anti-IL21R antibody and a soluble fragment of an IL-21R, to be used in the claimed method. Claims 15 and 16 recite that said antagonist soluble fragment of an IL-21R comprises an extracellular region of an IL-21 receptor, and that said antagonist comprises at least 85% identity to amino acid 20-235 of SEQ ID NO:4. Thus, these claims are drawn to a genus of antagonists that include antibodies to IL-21, antigen fragments of anti-IL-21 antibodies and fragments of soluble IL-21receptor. Applicants have described the soluble IL-21 receptor as having amino acid residues 20-235 of SEQ ID No:4. However, the claims encompass antagonists that vary substantially in composition, with no requirement for any particular structural feature. The disclosure of the polypeptide of SEQ ID NO:4, does not adequately describe the scope of the recited genus of antagonists to be used in the claimed method. Moreover, the description of the soluble IL-21 receptor comprising amino acid residues 20-235 of SEQ ID NO: 4, is not adequate written description of an entire genus comprising 85% identity to said polypeptide. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is the recitation of functional property of the antagonists to be used in the claimed method. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the

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scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The specification discloses two isolated cDNA sequences and the translated amino acid sequences. There is no description of the required structural features or conserved regions that the antagonist to be used should have that would be critical for practicing the claimed method. Since these features are not disclosed, there is no way to determine what variations could be tolerated without altering them. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the antagonist encompassed. Furthermore, although, antibodies are excellent reagents to localize receptors, they have to be raised against the appropriate epitopes, in order to effectively interfere the ligand/receptor interaction. Moreover, anti-receptor antibodies can act both as agonists and as antagonists, depending on what conformational changes the antibody induces on the receptor, (see Mijares et al, Molecular Pharmacology, 2000, Vol.58, pages 373-379, especially abstract and page 377). In the instant case, Applicants do not disclose a method using an anti-IL21 receptor antibody in the claimed method, to antagonize the IL-21/IL21receptor interaction.

Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that applicant was in possession of recited IL-21 /IL-21 receptor antagonists, other than the soluble IL-21 receptor comprising the amino acid residues 20-235 of SEQ ID NO:4.

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Claim Rejections Under § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3a. Claims 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Claims 1 and 16 do not recite any positive steps for the claimed method. The claims do not recite how is the inhibition of differentiation of Th precursor cells is being measured.

Claims 12, 14-23 are rejected under 35 U.S.C. § 112, second paragraph so far as they depend on claim 11 and 13 for the limitations set forth directly above.

Conclusion:

4. No claim is allowed.

Advisory Information:


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
25 July 2005



JOSEPH MURPHY
PATENT EXAMINER